IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED and ALLERGAN USA, INC. Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMA GLOBAL FZE Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan Pharmaceuticals International Limited ("Allergan Pharma") and Allergan USA, Inc. ("Allergan USA") (collectively, "Allergan" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Indus."), and Sun Pharma Global FZE ("Sun Global") (collectively, "Sun"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq*., arises from Sun's submission of Abbreviated New Drug Application ("ANDA") No. 214718 ("Sun's ANDA") to the United States Food and Drug Administration ("FDA"). Through Sun's ANDA, Sun seeks approval to market a generic version of Plaintiffs' pharmaceutical product ASACOL® HD prior to the expiration of United

States Patent No. 9,089,492 ("the '492 Patent"). Plaintiffs seek injunctive relief precluding infringement, and any other relief the Court deems just and proper.

PARTIES

2. Plaintiff Allergan Pharma is a private company limited by shares under the laws of Ireland and having a registered office at Clonshaugh Business and Technology Park, Coolock, Dublin 17 Ireland. Allergan Pharma holds New Drug Application ("NDA") No. 021830, under which the FDA approved the marketing of ASACOL® HD for the treatment of moderately active ulcerative colitis in adults. Allergan Pharma is an affiliate of AbbVie Inc., a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400.

3. Plaintiff Allergan USA is Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940. Allergan USA is an affiliate of AbbVie Inc.

4. On information and belief, Defendant Sun Ltd. is a corporation organized and existing under the laws of India, having a place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063 India. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating subsidiaries, including Sun Indus. and Sun Global.

5. On information and belief, Defendant Sun Indus. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in New Jersey at the following business address: 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun Indus. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and

importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

6. On information and belief, Defendant Sun Global is a corporation organized and existing under the laws of the United Arab Emirates, with a principal place of business at Office 43 Block Y, Sharjah Airport International Free Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

7. On information and belief, Sun Indus. and Sun Global are wholly owned subsidiaries of Sun Ltd., and act in concert with Sun Ltd. to develop, manufacture, produce, distribute, and sell generic drugs. On further information and belief, Sun Indus. and Sun Global market, sell, and distribute generic drugs manufactured and supplied by Sun Ltd. throughout the United States, including in this judicial district.

8. On information and belief, Sun Indus. and Sun Global act at the direction, and for the benefit, of Sun Ltd., and are controlled and/or dominated by Sun Ltd. On further information and belief, Sun Ltd., Sun Indus., and Sun Global are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

9. On information and belief, Sun caused Sun's ANDA to be submitted to FDA and seek FDA approval of Sun's ANDA.

10. On information and belief, Sun Ltd. holds Drug Master File ("DMF") No. 29575 for mesalamine.

11. On information and belief, Sun Ltd. and Sun Indus. collaborated in the preparation and submission of Sun's ANDA and DMF No. 29575 and continue to collaborate in

pursuing FDA approval of Sun's ANDA and seeking to market its proposed generic mesalamine delayed-release tablets 800 mg (e.g., "ANDA Product").

12. On information and belief, Sun intends to commercially manufacture, market, offer for sale, and sell Sun's ANDA Product throughout the United States, including in New Jersey, in the event FDA approves Sun's ANDA.

13. On information and belief, Sun Ltd., Sun Indus., and Sun Global rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in New Jersey. On information and belief, Sun Ltd., Sun Indus., and Sun Global intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Sun's ANDA Product, in the event FDA approves Sun's ANDA.

JURISDICTION AND VENUE

14. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '492 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

15. This Court has personal jurisdiction over Sun because, on information and belief, Sun, *inter alia*, has continuous and systematic contacts with New Jersey, regularly conducts business in New Jersey, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in New Jersey, and intends to sell Sun's ANDA Product in New Jersey upon approval of ANDA No. 214718.

16. On information and belief, Sun is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic

drug products, either directly or through subsidiaries, agents, and/or alter egos, which Sun manufactures, distributes, markets and/or sells throughout the United States and in this judicial district.

17. On information and belief, Sun is licensed to sell generic and proprietary pharmaceutical products in New Jersey, either directly or through on or more of its wholly owned subsidiaries, agents, and/or alter egos.

18. On information and belief, Sun has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufactures and/or markets ASACOL® HD for sale and use throughout the United States, including in this judicial district. On information and belief, and as indicated by a letter dated June 23, 2020, sent by Sun to, *inter alia*, Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(b) ("Sun's Notice Letter"), Sun prepared and filed its ANDA with the intention of seeking to market its ANDA Product nationwide, including within this judicial district.

19. On information and belief, Sun plans to sell its ANDA Product in New Jersey, list its ANDA Product on New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of its ANDA Product in the State of New Jersey, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Sun knows and intends that its proposed ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of ASACOL® HD, causing injury to Plaintiffs. Sun intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed ANDA Product.

21. Further, this Court has personal jurisdiction over Sun Indus. because Sun Indus. is a corporation having a principal place of business in New Jersey.

22. On information and belief, Sun Indus. is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5003437.

23. On information and belief, Sun Indus. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and 0100970132.

24. On information and belief, Sun Ltd. and Sun Indus. are amenable to litigating in this forum based on their conduct in other litigations in this district. For example, Sun Ltd. and Sun Indus. have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See, e.g.*, *Celgene Corp. v. Sun Pharm. Indus*., *Inc., Sun Pharm. Indus. Ltd., et al.*, No. 2:18- cv-11630- SDW-LDW (D.N.J. July 13, 2018); *Merck Sharp & Dohme Corp. et al. v. Sun Pharm. Indus., Inc. and Sun Pharma. Indus. Ltd.*, No. 2:20-cv-03007-CCC-CMF (D.N.J. Mar. 18, 2020).

25. On information and belief, Sun Global is amenable to litigating in this forum based on its conduct in other litigations in this district. For example, Sun Global has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *The Medicines Co. v. Sun Pharma Global FZE, et al.*, No. 3:11-cv-06819-PGS-DEA (D.N.J. Nov. 21, 2011); *Novartis Pharm. Corp., et al. v. Sun Pharma Global FZE, et al.*, No. 2:12-cv-04393-SDW-MCA (D.N.J. Jul. 14, 2012).

26. Additionally, this Court has personal jurisdiction over Sun Ltd. and Sun Global because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. and Sun Global are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Sun Ltd. and Sun Global have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Sun's ANDA, preparing and submitting DMF No. 29575 to FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Sun Ltd. and Sun Global satisfies due process.

27. Venue is proper in this district for Sun Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

28. Venue is proper in this district for Sun Global pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Global is a corporation organized and existing under the laws of the United Arab Emirates and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

29. Venue is proper in this district for Sun Indus. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Indus. is subject to personal jurisdiction and has a principal place of business in this judicial district.

ALLERGAN'S APPROVED DRUG PRODUCT

30. Allergan Pharma is the holder of an approved new drug application, NDA No. 021830, for a delayed-release oral tablet containing 800 mg of mesalamine. The NDA was first approved by FDA on May 29, 2008, and Allergan USA sells the approved drug product

under the tradename ASACOL® HD. ASACOL® HD is approved for the treatment of moderately active ulcerative colitis in adults.

31. FDA has listed, *inter alia*, the '492 patent in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 021830.

32. The '492 Patent qualifies for listing in the Orange Book in connection with NDA No. 021830 because it individually claims the approved drug product and/or an approved use of the drug product that is the subject of that NDA. Sun has never challenged the listing of the '492 Patent in the Orange Book.

SUN'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

33. Upon information and belief, on or before June 23, 2020, Sun Ltd. submitted to FDA its ANDA No. 214718 and a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for Sun's ANDA Product purportedly bioequivalent to ASACOL® HD. The purpose of the ANDA and paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of Sun's ANDA Product before the expiration of the patents listed in the Orange Book for NDA No. 021830.

34. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 214718 for Sun's ANDA Product is the treatment of moderately active ulcerative colitis in adults, i.e., the same indication as that set forth in the approved labeling for ASACOL® HD.

35. Upon information and belief, Sun sent Plaintiffs its Notice Letter dated June 23, 2020. The Notice Letter represented that Sun had submitted to FDA ANDA No. 214718 and purported paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the

FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for an 800 mg mesalamine delayed release tablet that is purportedly bioequivalent to Allergan Pharma's ASACOL® HD tablet.

36. Upon information and belief, the purpose of the ANDA and purported paragraph IV certification was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of Sun's delayed release tablet containing mesalamine before the expiration of the patents listed in the Orange Book for NDA No. 021830. Hence, Sun's purpose in submitting the ANDA is to market products described therein before expiration of the '492, '662, and '302 Patents.

37. In the Notice Letter, Sun did not contest infringement of any claim of the '492 Patent.

38. Plaintiffs bring this action within forty-five days of receipt of the Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 21 U.S.C. § 355(j)(5)(F)(ii).

COUNT I:
INFRINGEMENT OF THE '492 PATENT

39. Plaintiffs state, reallege, and incorporate by reference the foregoing paragraphs 1–38 as if fully set forth herein.

40. On July 28, 2015, the United States Patent and Trademark Office duly and legally issued the '492 Patent, titled "Pharmaceutical Dosage Form with Multiple Coatings for Reduced Impact of Coating Fractures." A true and correct copy of the '492 patent is attached hereto as Exhibit A.

41. Allergan Pharma is the owner of the '492 Patent, having acquired the entire right, title, and interest in the '492 Patent from Warner Chilcott Company, LLC on or about December 31, 2015.

42. Allergan USA currently sells ASACOL® HD in the United States. ASACOL® HD and/or its approved conditions of use fall within one or more of the claims of the '492 Patent.

43. As owner of the '492 Patent, Allergan Pharma is authorized to enforce the '492 Patent.

44. On information and belief, Sun Ltd. has submitted or caused the submission of Sun's ANDA to the FDA, and continues to seek FDA approval of Sun's ANDA.

45. Sun's ANDA Product infringes one or more claims of the '492 Patent.

46. Sun's Notice Letter does not contest infringement of any claim of the '492 Patent. If Sun had a factual or legal basis to contest infringement of any claims of the '492 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

47. Sun's ANDA Product for which Sun seeks approval in ANDA No. 214718 falls within one or more of the claims of the '492 Patent. If approved, the importation, manufacture, sale, offer for sale or use of Sun's ANDA Product that is the subject of ANDA No. 214718 would infringe one or more of the claims of the '492 Patent.

48. On information and belief, the conditions of use for Sun's ANDA Product for which Sun seeks approval in ANDA No. 214718 fall within one or more of the claims of the '492 Patent. If approved, use of Sun's ANDA Product in accordance with the proposed labeling submitted in ANDA No. 214718 would infringe one or more of the claims of the '492 Patent.

49. Sun is liable for infringement of the '492 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 214718 with a paragraph IV certification seeking FDA approval of ANDA No. 214718.

50. The importation, manufacture, sale, offer for sale, or use in the United States of Sun's ANDA Product proposed and intended by Sun would infringe one or more claims of the '492 Patent, and Sun would be liable for direct infringement under 35 U.S.C. § 271(a).

51. Unless enjoined by this Court, upon FDA approval, Sun will actively induce infringement of the '492 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Sun's ANDA, Sun will make, use, offer to sell, or sell Sun's ANDA Product within the United States, or will import Sun's ANDA Product into the United States, and will thereby induce infringement of one or more claims of the '492 Patent. On information and belief, upon FDA approval, Sun will intentionally encourage acts of direct infringement with knowledge of the '492 Patent and knowledge that its acts are encouraging infringement.

52. Unless enjoined by this Court, upon FDA approval, Sun will contributorily infringe the '492 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Sun's ANDA, Sun will offer to sell or sell Sun's ANDA Product within the United States, or will import Sun's ANDA Product into the United States, and will thereby contribute to the infringement of one or more claims of the '492 Patent. On information and belief, Sun has had and continues to have knowledge of the '492 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Sun has had and continues to have knowledge that Sun's ANDA Product is especially made or especially adapted for a use that infringes the '492 Patent and that there are no substantial noninfringing uses for Sun's ANDA Product.

53. Sun had actual and constructive notice of the '492 Patent prior to filing the Sun ANDA, and was aware that the filing of the Sun ANDA with the request for FDA approval

prior to the expiration of the '492 Patent would constitute an act of infringement of the '492 Patent.

54. Sun filed its ANDA without adequate justification for asserting that the '492 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity with respect to the '492 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

55. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing and contributing to the infringement of the '492 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Sun has infringed the '492 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the last expiration date of the '492 Patent, or any later expiration of exclusivity for the '492 Patent, including any extensions or regulatory exclusives;

C. Entry of a permanent injunction, enjoining Sun and its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Sun or on its behalf from commercially manufacturing,

using, offering for sale, or selling its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the '492 Patent, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '492 Patent;

D. A judgment declaring that making, using, selling, offering to sell, or importing Sun's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '492 Patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Sun engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the '492 Patent, or induces or contributes to such conduct, prior to the expiration of the patent including any additional exclusivity period applicable to this patent;

F. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. Costs and expenses in this action; and

H. Such other and further relief as the Court deems just and proper.

Dated: August 7, 2020

Respectfully submitted,

WALSH PIZZI O'REILLY FALANGA LLP

/s/ Liza M. Walsh

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Local Rule 11.2 Certification

We hereby certify that, to the best of our knowledge, the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding.

Dated: August 7, 2020

WALSH PIZZI O'REILLY FALANGA LLP

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Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: August 7, 2020

WALSH PIZZI O'REILLY FALANGA LLP

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